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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/516,493	03/01/2000	Maureen J. Charron	96700/613	3363

7590 08/12/2003

Craig J. Arnold eSQ
Amster Rothstein & Ebenstein
90 Park Avenue
New York, NY 10016

EXAMINER	
KAUSHAL, SUMESH	
ART UNIT	PAPER NUMBER
1636	22

DATE MAILED: 08/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/516,493	CHARRON ET AL.	
	Examin r	Art Unit	
	Sumesh Kaushal Ph.D.	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 May 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *73-115* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *73-115* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *19* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's response filed on 05/23/03 has been acknowledged.

Claims 73-75 are amended.
Claims 80-91, 95-97, 101-103, 107-109 and 113-115 are canceled.
Claims 73-79, 92-94, 98-106 and 110-112 are pending and are examined in this office action.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The references cited herein are of record in a prior Office action.

▷ *Applicants are advised to follow Amendment Practice under revised 37 CFR §1.121 (http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/revamdtprac.htm).*

Claim Rejections - 35 USC § 101 & 35 USC § 112

Claims *73-79, 92-94, 98-106 and 110-112* stand rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted **utility** or a well established utility, for the same reasons of record as set forth in the office action mailed on 03/11/03.

Claims *73-79, 92-94, 98-106 and 110-112* stand rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know **how to use the claimed invention,** for the same reasons of record as set forth in the office action mailed on 03/11/03.

Response to arguments

The applicant argues that invention has utility as marker of hyperglycemia and diabetes and in the diagnosis of breast cancer. The applicant argues that specification discloses that the livers and placentas of diabetic and hyperglycemic animals show 2-3 fold up regulation of the nucleotide sequences as claimed. Therefore claimed nucleic acid sequences have specific, credible and substantial utility as a marker of diabetes or hyperglycemia. The applicant argues that since GLUTx protein is expressed in mammary tumors and not in normal mammary tissue,

the subject of invention also has utility for the detection of breast cancer. The applicant argues that detection of GLUTx protein in a mammary tumor as determined by Western blot analysis would be an indication that subject has breast cancer. The applicant further argues that an applicant need to provide only one credible assertion of specific and substantial utility for each claimed invention (response, page 7 para.2). Based upon these observations the applicant concluded that invention as claimed have specific, substantial and credible utility (response, page 8 para.2-3).

However, this is found NOT persuasive. The applicant's argument alone is not evidence that the invention as claimed have any specific utility, since the applicant fails to establish that invention as claimed has any real world utility explicitly or implicitly as putatively considered by the applicant. The 2-3 folds up-regulation of the claimed nucleic acid sequences in the liver of diabetic and hypoglycemic animal is not tissue-specific, since the instant specification clearly discloses the expression of GLUTx mRNA in variety of tissues including brain, liver and testis of both normal and diabetic rats (spec. page 39). Furthermore, considering the applicant's disclosure it is even unclear that there are any differences in the GLUTx in the liver of diabetic and hypoglycemic animals. The data presented in the instant specification even fails to support applicant's assertion (see fig-8). Fig-8 discloses a very low expression of GLUTx mRNA transcripts in the liver of both normal and diabetic animals. In addition use of GLUTx antibodies to diagnose the breast cancer is not specific, since GLUTx protein is not limited to breast cancer tissue. GLUTx has also been found to express in testis, heart fat, liver, diaphragm and soleus muscles in both GLUT4 null and wild type mice (spec. page 39). In addition GLUTx has also been known to express in both brown and white adipose tissue (see fig-2). Since the breast tissues mainly comprises of adipose tissue, it is unclear how one skill in the art would specifically diagnose a breast cancer tissue form a non-cancerous form based upon GLUTx expression in breast tissue biopsy. Therefore, specification fails to provide any credible evidence, which establishes that over expression of GLUTx protein is the maker for the diagnosis of breast cancer or diabetes explicitly or implicitly as putatively considered by the applicant. It is noted that patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable (*See Brenner v. Manson, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966), Stating, in context of the utility requirement, that*

"a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion") Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention. In instant case assigning a nucleotide sequence as maker for diabetes or breast cancer without any specific and substantial evidence is not considered routine in the art and without a specific and substantial disclosure the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). Since the invention as claimed does not have any specific and substantial utility, one skill in the art would have to engage in excessive and undue amount of experimentation to exercise the invention as claimed. The quantity of experimentation required would include the functional characterization of polypeptide encoded by SEQ ID NO: 7, 10 and 12 as a protein having glucose transporter/sensor/receptor (GLUT) like activity and use thereof.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sumesh Kaushal Ph.D. whose telephone number is 703-305-6838. The examiner can normally be reached on Mon-Fri. from 9AM-5PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yucel Irem Ph.D. can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-8724 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

S. Kaushal
PATENT EXAMINER

JEFFREY FREDMAN
PRIMARY EXAMINER